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Implantable device

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IMPLANTABLE DEVICE

The present invention relates to an implantable device to be used as an artificial fenestrum implantable in a bony wall of an inner ear, said device comprising a frame made of a bio-compatible material and provided to be applied at least partially in said bony wall, said frame being provided with a wall part, forming a barrier with a perilymph of said inner ear, when applied in said bony wall.

Such an implantable device is known from US-PS 5,772,575. The known device is part of an implantable hearing aid provided to be implanted in a temporal bone of a human being. The known hearing aid comprises a micro-actuator which includes a disk-shaped transducer which is attached to an end of a tube forming the frame of the implantable device. The tube comprises external threads enabling the tube to be screwed into a fenestration formed through the promontory of the middle ear cavity. The transducer is fabricated from a thin circular disk of stress-biased lead lanthanum zirconium titanate material. The transducer comprises two electrodes situated at opposite sides of the titanate material. Application of a potential difference across the electrodes causes the disk to become either more or less bowed, depending upon the polarity of the applied voltage. The transducer is soldered to one end of the tube, in such a manner that it faces the perilymph fluid of the cochlea. Since the transducer comprises on both sides electrodes, the electrodes face the perilymph fluid. The transducer deflects when a voltage is applied across the electrodes thereby generating fluid vibrations within the perilymph fluid at the frequency of the applied voltage. Preferably, a very thin metallic diaphragm, having a rim is hermetically sealed on the end of the tube. The disk-shaped transducer is contained entirely within the tube and is conductively attached to the diaphragm with a conductive cermet layer juxtaposed with the diaphragm. The diaphragm serves as a support for the disk-shaped transducer and deforms in conformity with the transducer.

Such devices are used for energy transfer to and from the inner ear and are suitable for diagnosis and treatment of a wide range of otological pathologies. In a normal hearing organ there exist two natural openings, also called windows, connecting the middle and the inner ear (one of them interfacing with the vibrating ossicular chain of the middle ear and the other one serving as a pressure equaliser).

Modification and/or amplification of the energy reaching the sensory cells of the inner ear is the basis for treatment of conductive and sensorineural hearing losses. First attempts to improve hearing by making a hole in the wall of the inner ear at the level of the lateral semicircular canal have been undertaken already in 1914 by Jenkins and improved by Lempert in 1938. This procedure, called "fenestration" (where a trough-shaped window made in the bony wall of the inner ear was covered with transposed tympanic membrane) attempted to connect the fluid spaces of the human inner ear directly to the outside world bypassing the dysfunctional middle ear. This procedure enabled the sound energy to reach directly the membranous part of the inner ear and could result in an improvement of hearing by up to 30dB.

Currently, when opening of the inner ear space is necessary, other - safer and more effective - surgical techniques have been developed. In patients with otosclerosis (immobility of the ossicular chain due to fixation of the stapes footplate) a small-hole fenestration in the stapes footplate is made and a Teflon piston is transposed between the incus and the opening in the footplate (after removal of the stapes superstructure). This procedure, albeit quite difficult technically, allows for normalisation of the functional status of the conductive part of the middle ear and in most cases is able to restore hearing to normal or quasi-normal.

Amplification of the energy reaching the sensory cells of the inner ear could also be achieved in a variety of hearing aids. All these devices try to compensate for the diminished hearing acuity by

amplification of the energy reaching the inner ear (either as the amplified sound wave in the air or as a vibration coupled to the ossicular chain or transferred through the bones of the skull). However, application of any one of these devices has important drawbacks - from cosmetic non-acceptance, feedback and distortion in classical hearing aid to limited indications and variable results in implantable hearing aids. There is no teaching in this prior art to couple the acoustic energy directly to the fluid spaces of the inner ear.

The Round Window Electromagnetic device (RWEM) realises coupling to the cochlear fluids through an intact round window membrane, which serves here as the natural flexible interface between the middle and the inner ear. The RWEM uses a magnet surgically placed onto the round window and an electromagnetic coil to induce vibration. This vibration is transmitted through an intact round window membrane into the coclea's fluids. The RWEM device, however, would compromise the normal compliance of the round window membrane, which could induce a hearing loss. There is no teaching in this prior art to make use of an artificial fenestration device.

Money (US-PS 5,782,744) proposed an implantable microphone encapsulated in a waterproof casing and placed at the round window in contact with the cochlear fluid, immersed in the cochlear fluid or placed in the middle ear and coupled to the inner ear fluid by a conduction tube. The advantage of such microphone is that it can precisely transmit the pressure variations induced in the inner ear by acoustic stimulation. Yet there is no teaching in this prior art to make this system suitable for mechanical stimulation of the cochlear fluids.

Gilman (US-PS 5,176,620) proposed transmission of acoustic energy between a remote pressure generator and the inner ear via a liquid filled tube terminated with a membrane and placed at the round window. There is however no teaching in this prior art to use a separate, universal device as the hermetic interface between the middle

and inner ear and allowing for connection with it of the transmission tube or other stimulating and/or sensing members.

5 A drawback of the known implantable device is that the tube applied on the promontory and the micro-actuator forms a whole. The transducer and its electrodes, which are part of the micro-actuator form a structural part of the tube. It is the transducer with its electrodes and with or without its diaphragm which forms the barrier between the inner volume of the tube and the perilymph fluid. There is no teaching to consider this barrier as a construction part of the frame and thus to make 10 the frame and the wall part a stand alone device capable to operate as an interface for the transfer of energy to and from the inner ear. Therefore this barrier is not galvanically insulated from the electrical signal applied on the electrodes in order to make the transducer vibrate and induce vibrations into the perilymph fluid. There is no teaching in this prior art to 15 electrically insulate this barrier from these electric signals. The known device is only suitable for electrically generating said vibrations directly within the transducer facing the perilymph fluid.

It is an object of the present invention to realise an implantable device to be used as an artificial fenestrum implantable in 20 the bony wall of the inner ear, enabling mechanical pressure as well as other manners to induce vibrations in said perilymph.

For this purpose, an implantable device according to the present invention is characterised in that said wall part is formed by a membrane made of a bio-compatible material, said membrane being 25 provided to form together with said frame an interface with said inner ear, said interface being provided for energy transfer, in particular mechanical and/or electrical and/or electromagnetic energy, towards said inner ear. By using a membrane made of bio-compatible material for the wall part forming the barrier with the perilymph, the whole device becomes a stand alone interface provided for energy transfer. The device can be used as 30 an interface for coupling of the physiological vibrations of the ossicular

chain to the inner ear or for connection of a vibratory actuator of an implantable hearing aid. It can also work in the reverse mode, serving as the membrane of a microphone or as a sensor of electrical potentials generated in the inner ear. In cases of oval and/or round window aplasia
5 It can aid to restore the mechanics of the inner ear. Another application is the Ménière's disease, where the device can be used for coupling of a diagnostic/treatment tool (measuring the pressures and potentials generated in the inner ear or generating e.g. pressure pulses).

A first preferred embodiment of a device according to the
10 invention is characterised in that said membrane is electrically dissociated from an electrical signal output circuitry of a vibration generator to be applied into said device. By having the membrane electrically dissociated from the electrical signal output circuitry, necessary to generate the vibrations into the perilymph fluid, it becomes
15 possible to apply other signals such as mechanical or pressure signals on the perilymph fluid. This set-up enables to mechanically and electrically dissociate the frame from the actuator or vibration generator, thus allowing to implant a large variety of actuators.

A second preferred embodiment of a device according to
20 the invention is characterised in that said membrane is provided to form a substantially hermetical closure between said perilymph and an inner part of said frame, when applied in said inner ear. By forming such an hermetical closure, contamination of the perilymph and the inner ear is substantially reduced.

A third preferred embodiment of a device according to the
25 invention is characterised in that a side of said membrane, provided to contact said perilymph when said device is mounted in said inner ear, is provided with an electrically conductive layer which is connected to a conductive wire, applied in an electrically insulated manner on said
30 frame. This enables to bring an electrode in direct contact with the

perilymph fluid without affecting the electrical insulation of the membrane.

5 A fourth preferred embodiment of a device according to the invention is characterised in that said device is provided with connecting means applied on said frame, said connecting means being provided for receiving and connecting a stimulating and/or a sensing member into said frame in such a manner as to enable said energy transfer. In such a manner, a stimulating and/or sensing member can easily be connected inside the frame.

10 Preferably, a mechanically driven piston is mounted into said frame, said piston being mounted in such a manner as to mechanically contact said membrane. Mechanically driven pistons provide a reliable and accurate pulse generator.

15 The invention will now be described in more details with reference to the annexed drawings illustrating a plurality of embodiments for an implantable device according to the present invention. In the drawings :

20 fig. 1 is a schematic coronal view through a human temporal bone illustrating the external, middle and inner ears and showing the relative position of the device in accordance with the present invention;

fig. 2 shows in a detailed manner how the device is implanted in the inner ear;

25 fig. 3 A to E show cross-sections of different embodiments of the implantable device of the present invention;

fig. 4 A shows a top view and fig. 4 B a side view of an implantable device of the present invention;

fig. 5 A to C show cross-sections of other embodiments of the device according to the present invention;

30 fig. 6 shows the device provided with an electromagnetic stimulating/sensing device;

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fig. 7 shows the device provided with a piezo-electric stimulating/sensing device,

fig. 8 shows the device provided with a fluid filled conduct serving for energy transmission from a remote transducer; and

5 fig. 9 and 10 show the device provided with a connection with the ossicular chain.

In the drawings, a same reference sign has been assigned to a same or analogous element.

10 Figure 1 illustrates relative locations of components of an implantable device 1 in accordance with the present invention after implantation in a temporal bone 2 of a human being. This figure also illustrates an external ear 3 with a pinna 4 and an external auditory canal 5. An opposite end of the external auditory canal ends at an ear drum or tympanic membrane 6, which forms an interface between the external
15 and the middle ear 7. The tympanic membrane 6 mechanically vibrates in response to sound waves travelling through the external auditory canal 5. The tympanic membrane amplifies sound waves by collecting them in a relatively large area and transmitting them to a much smaller area of an oval-shaped window 8.

20 The middle ear 7 is an air filled space comprising three ossicles, namely a hammer 9, connected with a shaft 10 to the tympanic membrane 6, an incus 11 and stapes 12, forming an ossicular chain responsible for sound transmission to the inner ear 13. The latter is located in the medial aspects of the temporal bone 2. The inner ear
25 comprises an otic capsule bone containing semicircular canals for balance on a cochlea 14 for hearing. A relatively large bone, called the promontory 15, projects from the otic capsule bone inferior to the oval window 8 which overlies a basal coil of the cochlea 14. A round window 16 is located at the opposite side of the promontory 15 from the oval
30 window 8 and overlies a basal end of the scala tympane.

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The vestibule 20 communicates with the middle ear 7 through two openings, namely the oval window 8 and the round window 16. The oval window is the receptacle for the footplate of the stapes 12, which is flexibly suspended by means of an annular ligament. The round window 16 is closed and isolated from the middle ear by a thin flexible round window membrane.

The hammer 9, the incus 11 and the stapes 12 form the ossicular chain and span the middle ear cavity 7 to connect the tympanic membrane with the inner ear 13 at the oval window 8. The ossicular chain conveys mechanical vibrations of the tympanic membrane to the inner ear 13, mechanically de-amplifying the motion by a factor of 2.2 at 1000 Hz. Vibrations of a stapes footplate 12 in the oval window 8 will cause a perilymph fluid 17 present in the scala vestibule of the cochlea 14 to vibrate. These pressure wave vibrations travel through the perilymph fluid 17 and endolymph fluid of the cochlea 14 to produce a travelling wave of the basilar membrane. Displacement of the basilar membrane bends "cilia" of the receptor cells 18. The shearing effect of the cilia on the receptor cells 18 causes depolarisation of the receptor cells 18, which on its turn causes auditory signals to travel in a highly organised manner along auditory nerve fibres 19, through the brainstem to eventually signal a temporal lobe of a brain of the human being to perceive the vibrations as sound.

The vestibule 20 forms together with the anterior 21, the posterior 22 and the lateral 23 semicircular canals, part of the inner ear.

The two preferred localisations of the device 1 into the ear are also shown in figure 1. One is the wall of the promontorium 15 and the other one is in the wall of the lateral semicircular canal 23. The localisation in the wall of the promontorium 15 should be chosen in such a manner that it overlaps the scala vestibuli, well above the basilar membrane. Of course the device can be implanted in other locations of the inner ear than the one already mentioned. Such another location in

the bony wall is for example the oval niche. Figure 2 illustrates in detail how the device according to the invention is placed in the bony wall of the inner ear 13. The preferred implantation technique applies the device 1 in such a manner that it penetrates through the bony wall of the inner ear, thereby leaving the internal endosteum 25 intact. In this way the device has no direct contact with the fluid space of the perilymph thereby substantially decreasing the number of potential complications.

In order to apply the device in the bony wall, a fenestration is first drilled in this bony wall, without injuring the endosteal internal lining of the inner ear. The fenestration is preferably stepwise made by increasing the depth, using custom-made diamond drilling heads with increasing length. Such a technique reduces considerably the risk of introgenic complications such as infections or a loss of hearing. After creation of the fenestration, the device is applied therein for example by screwing either on the wall of the fenestration or on the upper part of the bony wall. The device is preferably applied by using a predetermined torque.

The device is made of a bio-compatible material such as for example titanium. The latter being particularly suitable for a direct, very strong connection with the bone tissue. The latter may even be improved by coating the frame of the device with antibiotics and/or a substance promoting bone tissue growth such as for example a hydroxyapatite.

Figure 3 A illustrates a cross section of a first embodiment of an implantable device 1 according to the invention. The device is preferably substantially cylindrically shaped and provided with a screw thread 32 on upstanding walls of the frame 30.

Inside the frame is a cavity 31, provided for receiving a stimulating and/or sensing member, as will be described hereinafter. The device preferably has a height of 3 to 4 mm and a diameter of approximately 2 mm. The frame is made of bio-compatible material such as for example titanium. The advantage of using titanium is that this

material oxides at its surface thus enabling a strong direct connection with the bone tissue.

A wall part of the frame is formed by a membrane 33, which is preferably thin and made of flexible bio-compatible material, such as for example titanium or silicone. The membrane and the rest of the frame together form an interface with the inner ear. The interface is provided for energy transfer from and towards the inner ear. The membrane is for example manufactured by spinning a silicone droplet using a spinning unit and connecting the thus obtained membrane with an external silicone ring 34 to the frame before full polymerisation is obtained. A further ring 38 could be applied on the frame in order to fix the membrane 33. The further ring 38 is either welded 35, for example by laser welding or screwed to the frame. The edges of the frame and the further ring 38 are preferably smoothed in order to avoid injury when implanting the device. The membrane is coupled to the frame and electrically dissociated or insulated from an electrical signal output circuitry of the vibration generator to be applied into the device.

The frame of the device is further provided with slots 36 applied on an upper peripheral of the frame as illustrated in figure 4. The slots are further preferably provided with inclined cut-outs 37 extending towards the inner side of the frame. The slots are provided for anchoring a mounting tool (not shown in the drawings) enabling to mount the device in the inner ear. The inclined cut-outs enable to provide protrusions on the mounting tool which are provided to fit into the cut-outs, thus enabling a better anchoring of the mounting tool into the slots.

The embodiment illustrated in figure 3 B distinguishes from the one illustrated in figure 3 A by a different fixing of the membrane to the frame. The silicone ring 34 of the membrane is only applied on the upper part of the membrane, in such a manner, that after application on the frame and welding the further ring 35, the membrane and the further ring are flush with the bottom part of the frame.

The embodiment illustrated in figure 3C comprises a membrane 33 having a C-shaped border and wherein the silicone ring 34 is applied on the upper side of the C-shaped border. The frame comprises an annular groove 39 applied on the external wall of the frame for accommodating the silicone ring 34. Also this embodiment enables a flush mounting of the membrane on the underside of the frame.

Figure 3 D shows an embodiment where the frame is provided with an inner groove 40 applied on an inner wall of the frame and provided for accommodating a peripheral wall of the membrane. The latter is laser welded to the inner groove when the membrane is made of metal.

The embodiment illustrated in figure 3 D is analogous to the one shown in figure 3 C but distinguishes by the presence of a further external annular groove 41 applied on an upper side of the external frame wall. An O-ring is housed in the further groove 41 enabling to fix a further device thereon.

In all the embodiments the membrane is provided to form a substantially hermetical closure between the perilymph, facing the outer side of the membrane and an inner part of the frame, with which the other side of the membrane is in contact. This hermetical closure provides an adequate protection of the perilymph fluid and avoids contamination.

Figure 5 A shows a cross-section of a further embodiment of a device according to the invention. The membrane is provided on its outer side, i.e. the side facing the perilymph, with an electrically conductive layer 42, which is connected to a conductive wire 44, applied in an electrically isolated manner on the frame 30. The isolation is for example realised by placing the wire 44 into a glass tube 43 extending through the frame from a top side thereof towards the bottom of the frame. The wire also crosses the membrane 33. Care is taken that the wire crosses the membrane in a fluid tight manner. The conductive layer

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42 is also made of a bio-compatible metal, for example platinum or gold, and is formed by a circular sheet fixed to the outer surface of the membrane. Alternatively the conductive layer could be obtained by direct metalisation of the silicone membrane. The metallic frame is also
5 conductive and forms a second electrode connected to a further wire 45.

The membrane 33 is electrically insulated from an electrical signal, produced by a sensing and/or stimulating device, as will be described in more detail hereinafter. The application of the conductive layer 42 enables to apply an electric signal directly to the perilymph,
10 without affecting the isolating function of the membrane.

In the embodiment illustrated in figure 5 B both sides of the membrane 33 are provided with a conductive layer 42 and 46 connected to each other by a connecting member 47 extending through the membrane. Both layers and the connecting member are made of bio-
15 compatible metal, for example platinum. The layers are preferably circularly shaped. They are fixed to the membrane by means of the connecting member 47 or obtained by direct metalisation of the membrane. The inner conductive layer 46 serves for electrical connection with a sensing and/or stimulating device.

Figure 5 C shows an embodiment where a conductive layer 48 is incorporated into the membrane 33 made of insulating material. In such a manner the membrane is co-axial with respect to the conductive layer 48.
20

Figure 6 illustrates in cross-section the device according to the present invention and provided with an electromagnetic sensing and/or stimulating member 50. In order to connect the latter member to the device, connecting means are applied on the frame. In the example illustrated in figure 6, the connecting means are formed by extending the frame 30 of the device, in such a manner, that the external screw thread
25 32 extends above the bony wall of the inner ear 13, when the device is applied in the inner ear. The sensing and/or stimulating member 50 is
30

lodged in a housing 51 provided with an internal screw thread 52, matching with the screw thread 32 of the device, in such a manner as to screw the housing 51 on the frame 30.

5 A coil 53 is placed inside the housing 51 and connected to wires 54 carrying a stimulating electrical current to be fed to the coil 53. The wires 54 are insulated from the frame 30 and the housing 51 for example by leading them through a glass tube 55 lodged in the housing. The stimulating current applied on the coil 53 causes a varying magnetic field to be created by the coil, causing on its turn the vibration of a piston
10 56 extending through the core of the coil.

The piston 56 could also be used as a sensing member. Movement of the piston will then cause AC currents to be induced into the coil 53. Those currents can then be picked up by the wires 54 and be led to an analyser. The piston is preferably made of Teflon (registered
15 trademark) and comprises a micromagnet 57 in its upper part. The upper surface of the piston is fixed to a flexible membrane 58, for example made of silicone, closing the central part of the housing 51. The other end of the piston 56 contacts the flexible membrane 33. Both ends of the piston are preferably rounded to ensure a better contact with the
20 respective membranes. The movement of the piston will then drive the membrane in order to transfer energy to the inner ear.

The membrane 58 serves two purposes, first the one to provide a flexible suspension to the piston 56 allowing it to vibrate and to transfer in such a manner vibratory energy to the membrane 33, and
25 secondly if the elasticity of membranes 58 and 33 matches, then this can be used for adjusting the pre-loading force exerted by the piston 56 on the membrane 33 when mounting the member 50. Observed increased bulging of the membrane 58 would correspond to the bulging of the membrane 33. When a membrane 33 with an electrical conductive layer
30 such as illustrated in figure 5 is used, another way to monitor a good contact between the piston 56 and the membrane 33 is the measurement

of the electrical resistance between the conductive layer on the membrane and the piston.

5 The membrane 33 is electrically insulated from the electrical signal applied on the coil as there is only a mechanical contact between the membrane 33 and the piston 56. The membrane thus serves as an interface between the piston and the perilymph and enables to transfer energy from and/to the perilymph to the member 50, without electrical contact between them.

10 Figure 7 illustrates in cross-section the device according to the present invention and provided with a piezo-electric sensing and/or stimulating member 60. The latter member is applied in a similar manner as the electromagnetic embodiment illustrated in figure 6. The housing 51 lodges a piezo-electric transducer 61 housed in a bottom part of a piston 62. Electrical wires 54 housed in a glass tube 55 are provided to
15 supply an electrical stimulating current to the piezo-electric transducer 61. The latter is mounted between two bio-compatible electrodes 63 a and b. The piezo-electric transducer 61 is for example made of stress-biassed lead lanthanum zirconia titanate (PLZT). A stimulating AC voltage supplied to the electrodes 63 causes the piezo-electric
20 transducer to vibrate, which vibrations are mechanically supplied to the membrane 33, since the piston 62 contacts mechanically the membrane 33. When used as a sensing member, the forces exerted on the piezo-electric transducer 61 by the vibration of the membrane 33, contacting the piston 62, will induce voltage at the sides of the piezo-electric
25 transducer. The latter is preferably rounded to ensure a better contact with the membrane 33. The pre-loading forces are controlled in an analogous manner as described with the electromagnetic embodiment.

30 Figure 8 shows an embodiment of the device according to the present invention in combination with a remote sensing and/or stimulating member. The coupling between the remote member and the membrane 33 is realised by means of a tube 65 filled with a fluid such as

for example liquid silicone. The tube is connected to one side with a remote transducer (not shown) and on the other side inserted into the frame of the device in order to mechanically contact the membrane 33. The tube 65 is hermetically closed with a further membrane 66 juxta-
5 posed to membrane 33. The tube is mounted in a housing 51 as previously described. The remote transducer is for example a piezo-electric or electromagnetic transducer but could also be a pressure generator.

Figure 9 shows an exemplary coupling of the ossicular
10 chain to the device according to the invention. This type of connection can be used e.g. in the cases of otosclerosis, where the footplate of the stapes 12 is fixed in the oval window 8, which results in immobility of the ossicular chain. In these cases, after removal of the stapes
15 superstructure (i.e. the head and the crura), the ossicular chain becomes mobile again. Then a prosthesis 85 can be placed between the long process 86 of the incus 11 and the membrane 33. The fragment of the prosthesis connecting to the incus 87 may be curved in such a way that it embraces the long process of the incus 86 and may be closed on it by
20 squeezing with microforceps. Such an approach allows to avoid opening of the stapes footplate which penetrates the perilymph. Also the connection with the membrane is easier due to a better access as well as more stable, since the construction of the device prevents migration of the distal end of the prosthesis 85.

Figure 10 shows another exemplary coupling of the
25 ossicular chain to the device according to the invention. This type of connection can be used for otosclerosis too, however it is also suitable for functional reconstructions in chronic middle ear pathologies with or without cholesteatoma. In these cases the ossicular chain is frequently disrupted and the remnants of it must be removed. Also in many cases
30 the stapes footplate in the oval window 8 is difficult to identify or it may be fixed. Therefore, in such cases, the prosthetic coupling 88 may be

realised between the device and the remnants of the shaft 10 of the hammer 9 or between the device and the native or grafted tympanic membrane 6. In the cases of chronic middle ear pathology performing a permanent opening penetrating from the middle ear 7 to the fluid space of the inner ear 13 is very dangerous and might in many cases result in infection of the inner ear 13 followed by fatal meningitis or total deafness. Therefore the concept of the device according to the invention which creates an interface for transfer of mechanical energy, yet still separates the middle and the inner ears with the membrane 33 offer a very attractive solution for these cases.

CLAIMS

1. An implantable device to be used as an artificial fenestrum implantable in a bony wall of an inner ear, said device comprising a frame made of a bio-compatible material and provided to be applied at least partially in said bony wall, said frame being provided with a wall part forming a barrier with a perilymph of said inner ear when applied in said bony wall, characterised in that said wall part is formed by a membrane made of a bio-compatible material, said membrane being provided to form together with said frame an interface with said inner ear, said interface being provided for energy transfer, in particular mechanical and/or electrical and/or electromagnetic energy, from and/or towards said inner ear.

2. An implantable device as claimed in claim 1, characterised in that said device is provided with connecting means applied on said frame, said connecting means being provided for receiving and connecting a stimulating and/or a sensing member into said frame in such a manner as to enable said energy transfer.

3. An implantable device as claimed in claim 1 or 2, characterised in that said membrane is provided to form a substantially hermetical closure between said perilymph and an inner part of said frame when applied in said inner ear.

4. An implantable device as claimed in any one of the claims 1 to 3, characterised in that a side of said membrane, provided to contact said perilymph when said device is mounted in said inner ear, is provided with electrically conductive means which are connected to a conductive wire applied in an electrically insulated manner on said frame.

5. An implantable device as claimed in any one of the claims 1 to 3, characterised in that a side of said membrane, provided to contact said perilymph when said device is mounted in said inner ear, is provided with electrically conductive means which are connected to said frame.

6. An implantable device as claimed in claim 1, characterised in that said membrane is coupled to the frame and electrically dissociated from an electrical signal output circuitry of a vibration generator to be applied into said device.

5 7. An implantable device as claimed in any one of the claims 1 to 6, characterised in that a mechanically driven piston is mounted into said frame, said piston being provided for generating pulses and being mounted in such a manner as to mechanically contact said membrane.

10 8. An implantable device as claimed in any one of the claims 1 to 6, characterised in that an electromagnetic stimulating and/or sensing member is mounted into said frame, said member comprising an electromagnetically driven actuator mechanically contacting said membrane within said frame.

15 9. An implantable device as claimed in any one of the claims 1 to 6, characterised in that a pressure generator is mounted into said frame, said pressure generator being provided for driving said membrane.

20 10. An implantable device as claimed in any one of the claims 1 to 6, characterised in that said frame is dimensioned in such a manner as to insert at least partially a stimulating and/or sensing member therein.

25 11. An implantable device as claimed in any one of the claims 1 to 10, characterised in that said device is substantially cylindrically shaped and provided with a screw thread on upstanding walls.

30 12. An implantable device as claimed in any one of the claims 1 to 6, characterised in that a piezo-electric stimulating and/or sensing member is mounted into said frame, said member comprising a piezo-electrically driven actuator mechanically contacting said membrane within said frame.

13. An Implantable device as claimed in any one of the claims 1 to 12, characterised in that said membrane is made of titanium.

14. An Implantable device as claimed in any one of the claims 1 to 13, characterised in that said frame is coated with antibiotics
5 and/or a substance promoting bone tissue growth, in particular

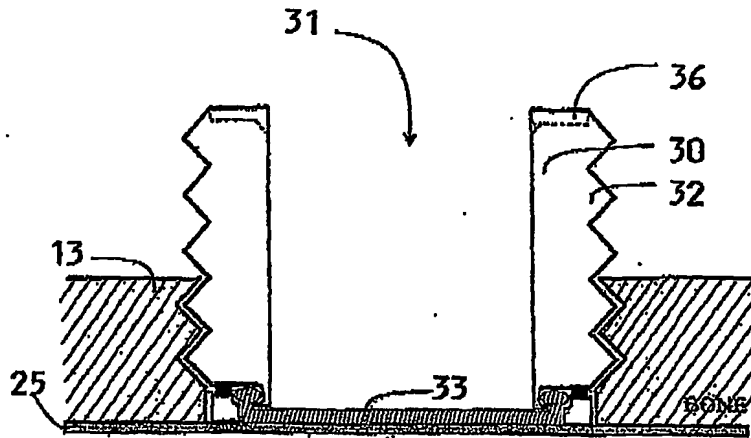


Fig. 2

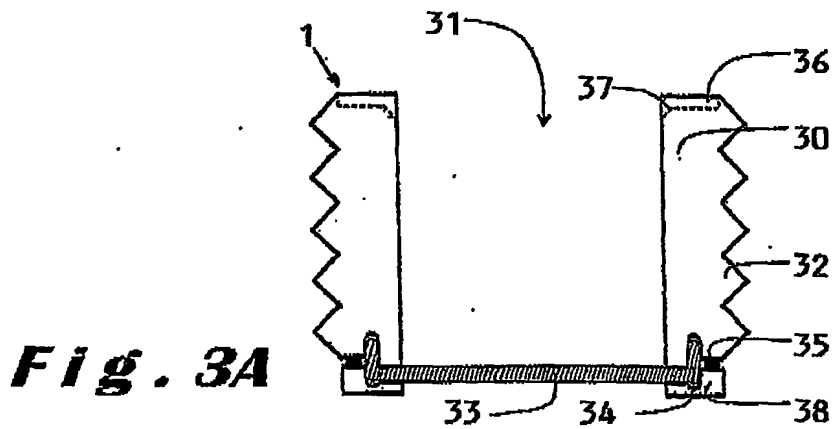


Fig. 3A

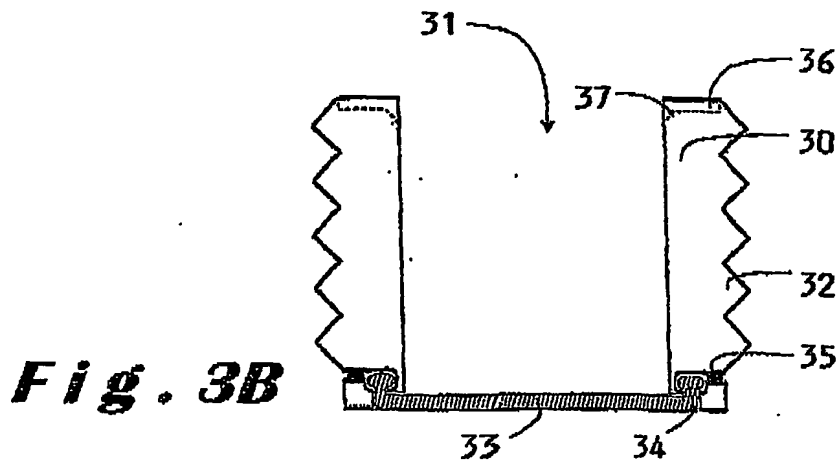


Fig. 3B

ABSTRACT**Implantable device**

5 An implantable device to be used as an artificial fenestrum implantable in
a bony wall of an inner ear, said device comprising a frame made of a
bio-compatible material and provided to be applied at least partially in
said bony wall, said frame being provided with a wall part forming a
barrier with a perilymph of said inner ear when applied in said bony wall,
said wall part is formed by a membrane made of a bio-compatible
material, said membrane being provided to form together with said frame
10 an interface with said inner ear, said interface being provided for energy
transfer, in particular mechanical and/or electrical and/or electromagnetic
energy, from and/or towards said inner ear.

Figure 2.

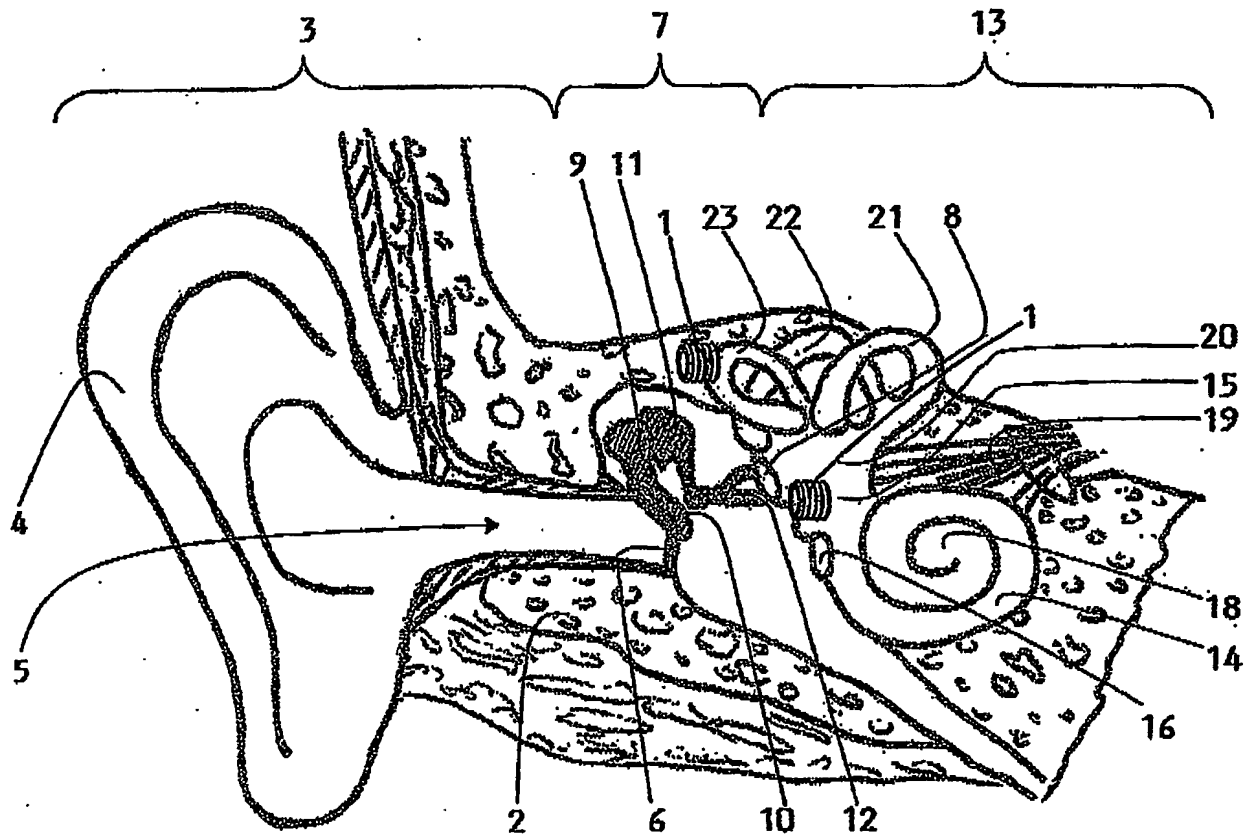


Fig. 1

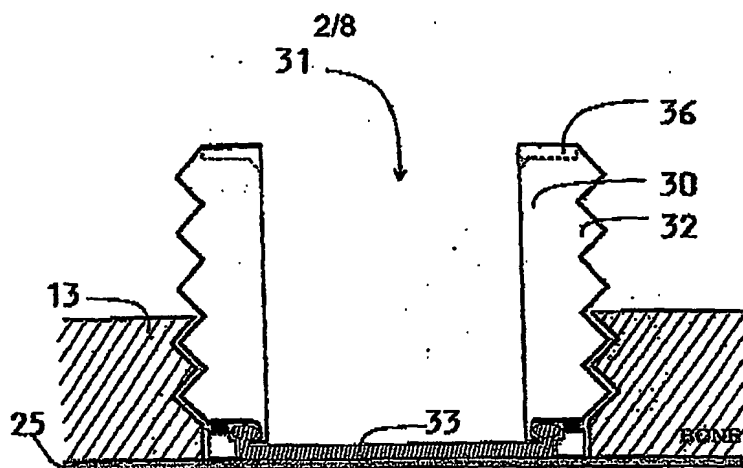


Fig. 2

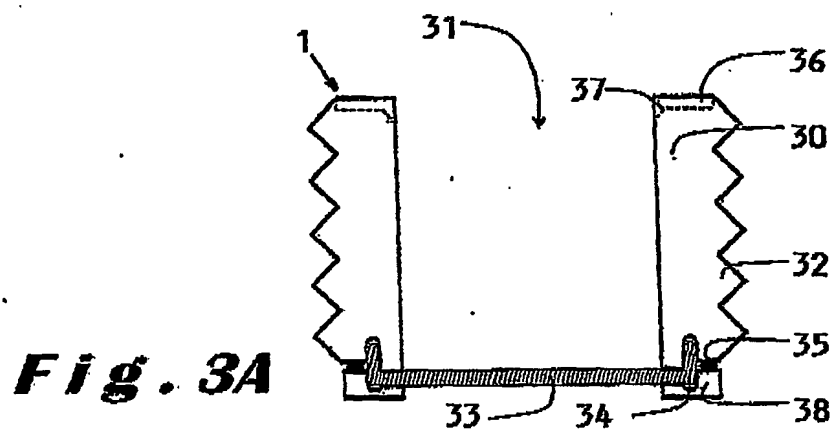


Fig. 3A

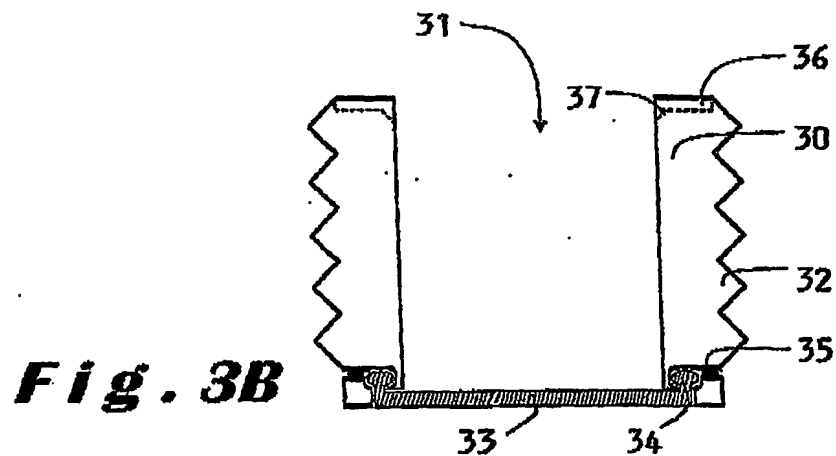
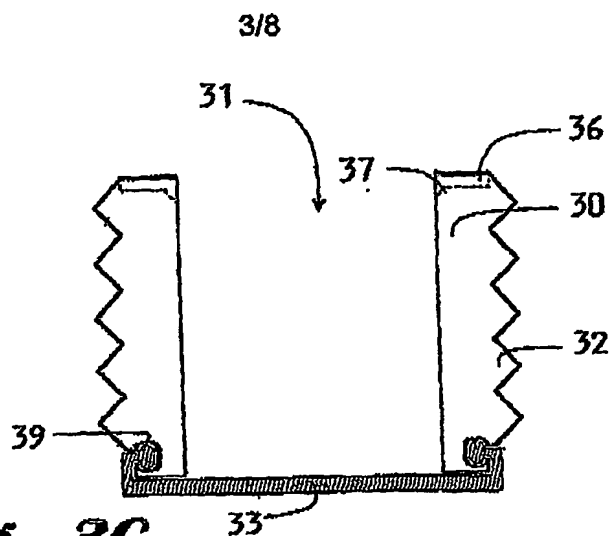
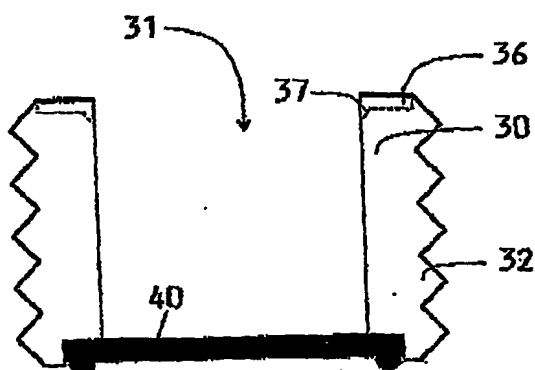
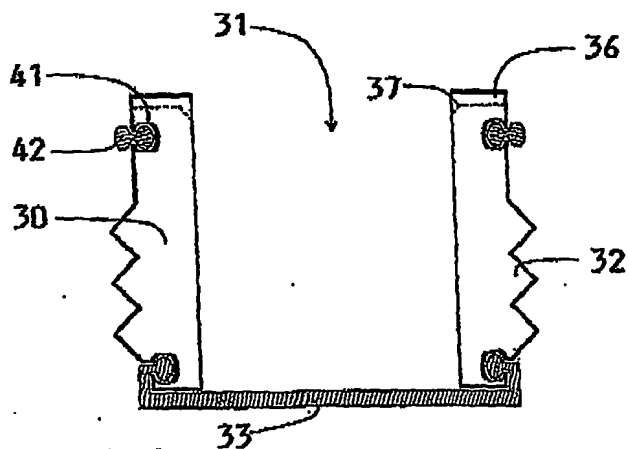
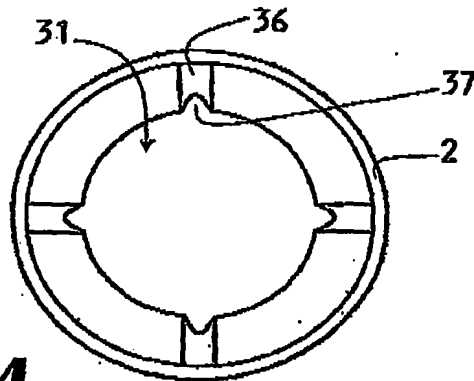
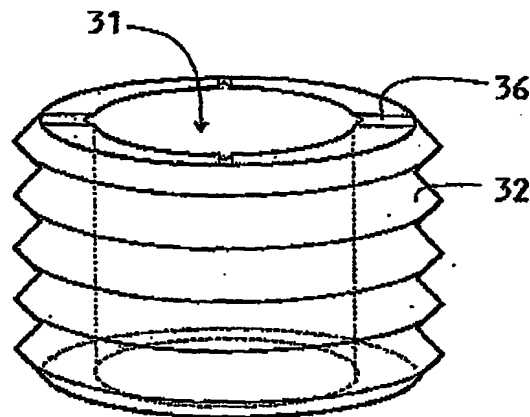
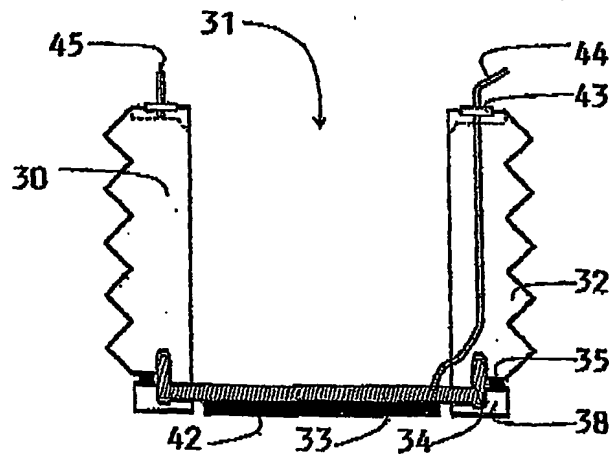
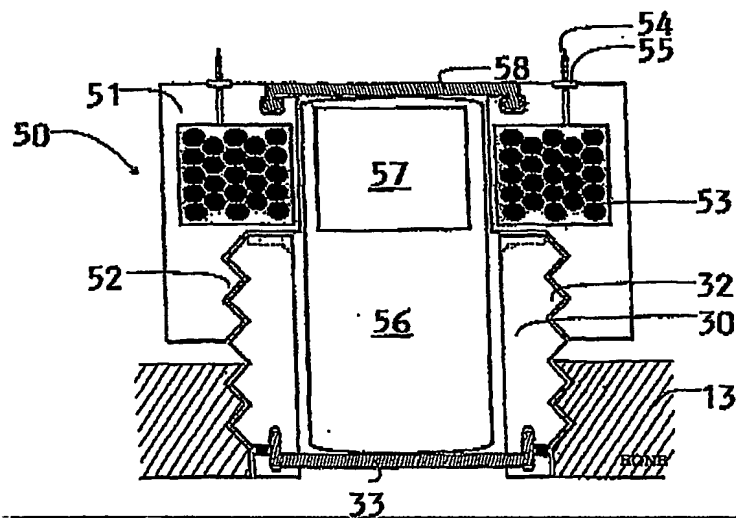
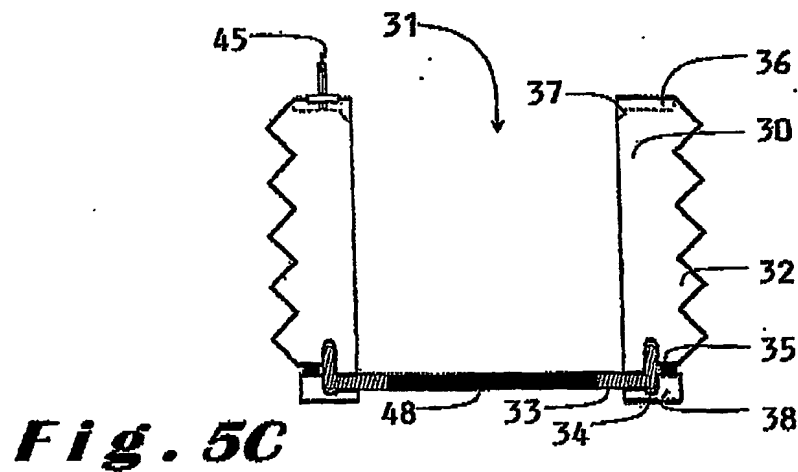
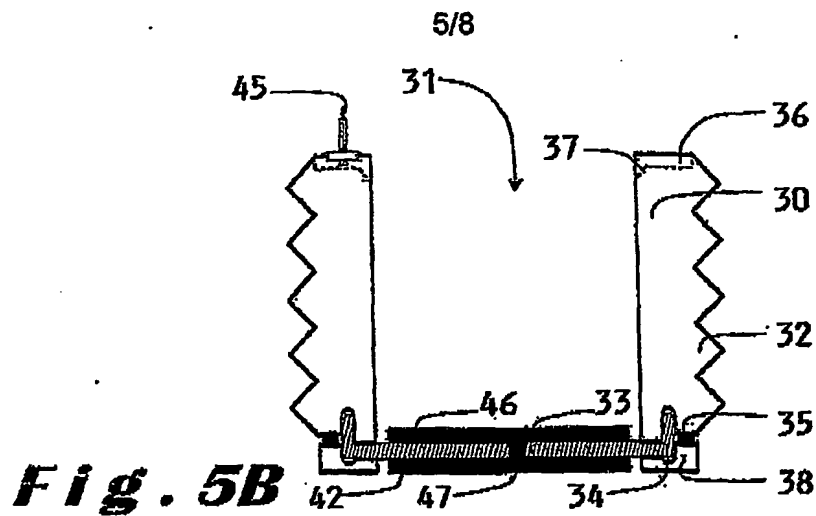


Fig. 3B

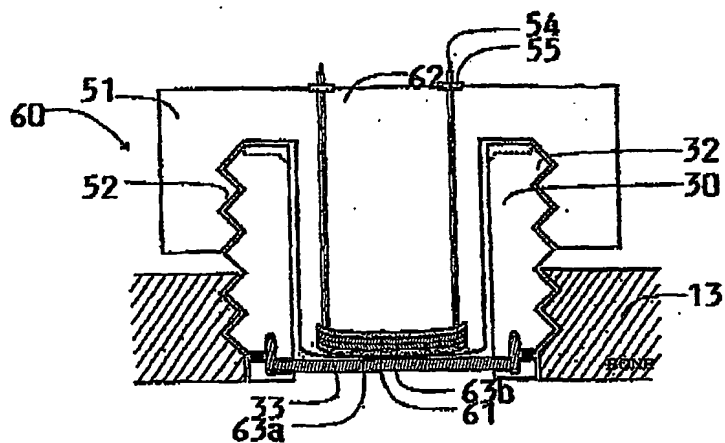
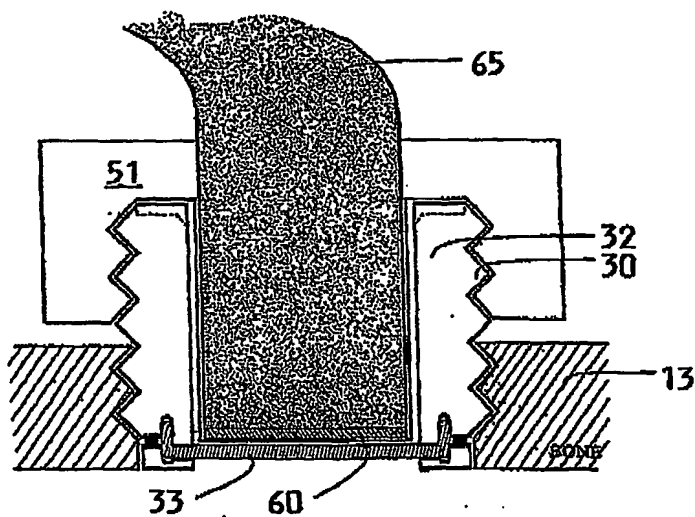
**Fig. 3C****Fig. 3D****Fig. 3E**

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**Fig. 4A****Fig. 4B****Fig. 5A**



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**Fig. 7****Fig. 8**

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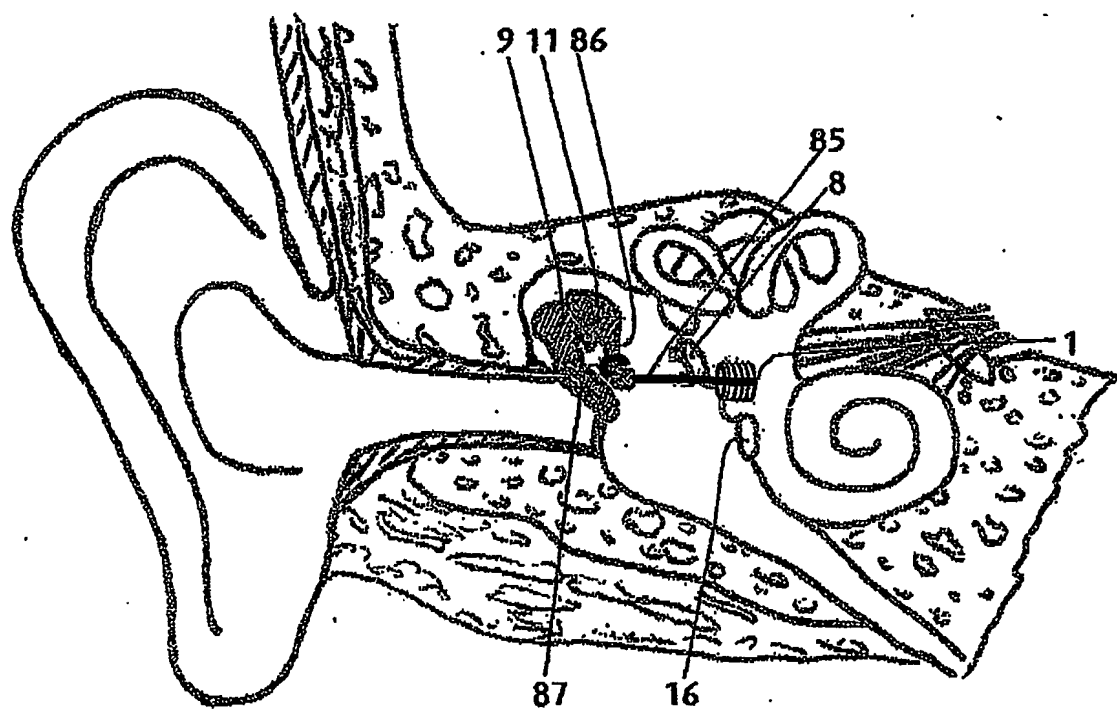


Fig. 9

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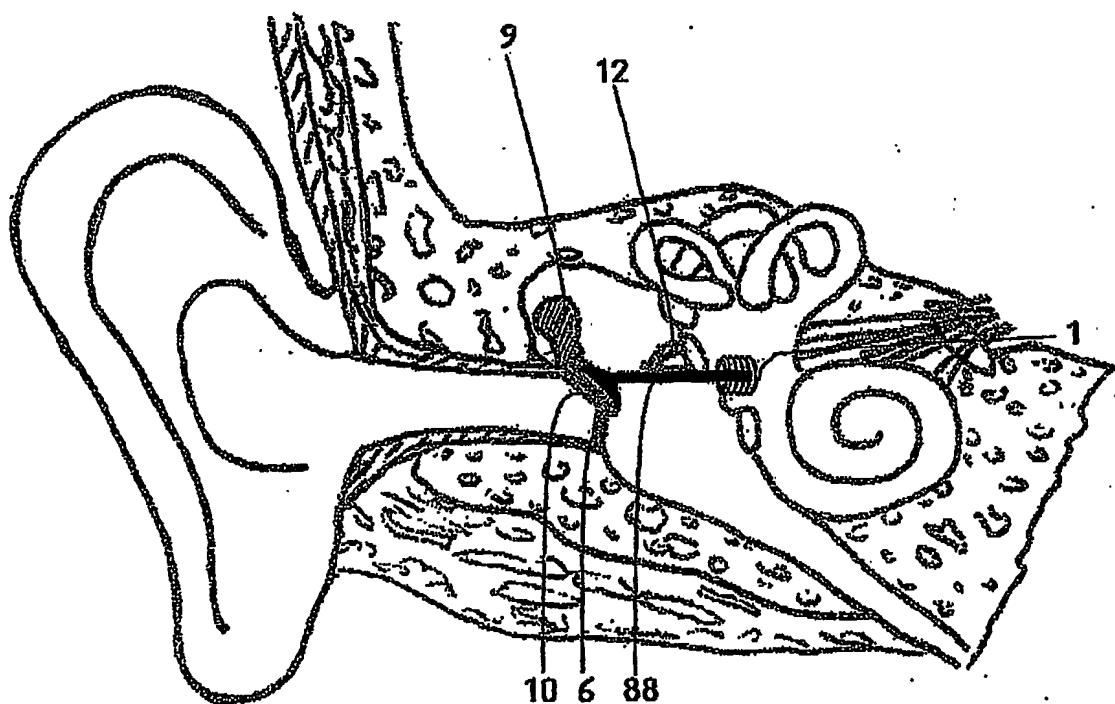


Fig. 10.

PCT Application
PCT/EP2003/014982



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